

(b) an aromatase inhibitor and a pharmaceutically acceptable carrier,  
pharmaceutically acceptable diluent, or combination thereof,

wherein said antineoplastic agent and said aromatase inhibitor are present in  
superadditive antitumor effective amounts,

and further wherein the aromatase inhibitor is not aminogluthetimide, when the  
antineoplastic agent is a combination consisting of cyclophosphamide, doxorubicin and 5-  
fluorouracyl.

25. (New) The pharmaceutical composition according to Claim 24, wherein the  
antineoplastic agent is selected from the group consisting of an antineoplastic topoisomerase  
II inhibitor, an antineoplastic antimicrotubule agent, an antineoplastic alkylating agent, an  
antineoplastic antimetabolite, and an antineoplastic topoisomerase I inhibitor, and the  
aromatase inhibitor is selected from the group consisting of exemestane, formestane,  
fadrozole, vorozole, letrozole, anastrozole and YM 511.

26. (New) The pharmaceutical composition according to Claim 24, wherein the  
antineoplastic agent is selected from the group consisting of an anthracycline compound, an  
anthraquinone compound, a podophillotoxine compound, a taxane compound, a vinca  
alkaloid, an alkylating agent, an antineoplastic antimetabolite agent and an antineoplastic  
topoisomerase I inhibitor.

27. (New) The pharmaceutical composition according to Claim 26, wherein the  
antineoplastic agent is selected from the group consisting of doxorubicin, epirubicin,  
idarubicin and nemorubicin; the anthraquinone compound is selected from the group  
consisting of mitoxantrone and losoxantrone; the podophillotoxine compound is selected  
from the group consisting of etoposide and teniposide; the taxane compound is selected from  
the group consisting of paclitaxel and docetaxel; the vinca alkaloid is selected from the group  
consisting of vinblastine and vinorelbine; the alkylating agent is selected from the group

consisting of cyclophosphamide, ifosfamide, melphalan and PNU 159548; the antineoplastic antimetabolite agent is selected from the group consisting of fluorouracil, capecitabine, gemcitabine, methotrexate and edatrexate; and the antineoplastic topoisomerase I inhibitor is selected from the group consisting of topotecan, irinotecan, 9-nitrocamptothecin and PNU 166148.

28. (New) The pharmaceutical composition according to claim 26, wherein said pharmaceutical composition comprises 1, 2 or 3 antineoplastic agents selected from the group consisting of epirubicin, doxorubicin, idarubicin, paclitaxel, docetaxel, 5-fluorouracil, cyclophosphamide and vinorelbine, and 1 or 2 steroidal aromatase inhibitors selected from the group consisting of exemestane, formestane, anastrozole, letrozole and fadrozole.

29. (New) The pharmaceutical composition according to claim 25, wherein the antineoplastic agent is selected from the group consisting of an anthracycline and a taxane compound, and the steroidal aromatase inhibitor is exemestane.

30. (New) The pharmaceutical composition according to Claim 28, wherein the composition comprises one or two antineoplastic agents selected from the group consisting of epirubicin and docetaxel, and the steroidal aromatase inhibitor is exemestane.

31. (New) The pharmaceutical composition, according to Claim 24, wherein:

- an effective antineoplastic amount of vinblastine is from about 3 mg/m<sup>2</sup> to about 10 mg/m<sup>2</sup>;
- an effective antineoplastic amount of doxorubicin is from about 20 mg/m<sup>2</sup> to about 100 mg/m<sup>2</sup>;
- an effective antineoplastic amount of epirubicin is from about 20 mg/m<sup>2</sup> to about 200 mg/m<sup>2</sup>;
- an effective antineoplastic amount of idarubicin is from about 1 mg/m<sup>2</sup> to about 50 mg/m<sup>2</sup>;

- an effective antineoplastic amount of mitoxantrone is from about 10 mg/m<sup>2</sup> to about 20 mg/m<sup>2</sup>;

- an effective antineoplastic amount of paclitaxel is from about 100 mg/m<sup>2</sup> to about 300 mg/m<sup>2</sup>;

- an effective antineoplastic amount of docetaxel is from about 50 mg/m<sup>2</sup> to about 100 mg/m<sup>2</sup>;

- an effective antineoplastic amount of vinorelbine is from about 15 mg/m<sup>2</sup> to about 30 mg/m<sup>2</sup>;

- an effective antineoplastic amount of cyclophosphamide is from about 100 mg/m<sup>2</sup> to about 1500 mg/m<sup>2</sup>;

- an effective antineoplastic amount of melphalan is from about 1 mg/m<sup>2</sup> to about 10 mg/m<sup>2</sup>;

- an effective antineoplastic amount of 5-fluorouracil is from about 100 mg/m<sup>2</sup> to about 1000 mg/m<sup>2</sup>;

- an effective antineoplastic amount of capecitabine is from about 10 mg/m<sup>2</sup> to about 1000 mg/m<sup>2</sup>;

- an effective antineoplastic amount of methotrexate is from about 10 mg/m<sup>2</sup> to about 1000 mg/m<sup>2</sup>;

- an effective antineoplastic amount of topotecan is from about 1 mg/m<sup>2</sup> to about 5 mg/m<sup>2</sup>;

- an effective antineoplastic amount of irinotecan is from about 50 mg/m<sup>2</sup> to about 350 mg/m<sup>2</sup>;

and an effective amount of aromatase inhibitor is from about 0.5 to about 500 mg.

32. (New) The pharmaceutical composition according to claim 31, wherein when administered orally, the amount of aromatase inhibitor exemestane is from about 5 to about

200 mg, the amount of fadrozole is from about 0.5 to about 10 mg, the amount of letrozole from about 0.5 to about 10 mg, and the amount of anastrozole is from about 0.5 to about 10 mg.

33. (New) The pharmaceutical composition according to claim 31, wherein when administered parenterally, the amount of aromatase inhibitor exemestane is from about 50 to about 500 mg, and the amount of formestane is from about 250 to about 500 mg.

34. (New) A pharmaceutical product comprising an antineoplastic agent and an aromatase inhibitor, wherein said agent and said inhibitor are present in amounts effective to produce a superadditive antitumor effect, and wherein the aromatase inhibitor is not aminogluthetimide when the antineoplastic agent is a combination consisting of cyclophosphamide, doxorubicin and 5-fluorouracyl, and wherein said product is capable of separate, simultaneous or sequential administration in breast cancer therapy in humans.

35. (New) A method for treating breast cancer in humans, said method comprising administering an antineoplastic agent to a human in need thereof and administering an aromatase inhibitor, in amounts effective to produce a superadditive antitumor effect, wherein the aromatase inhibitor is not aminogluthetimide when the antineoplastic agent is a combination consisting of cyclophosphamide, doxorubicin and 5-fluorouracyl.

36. (New) A method for treating breast cancer in humans, said method comprising administering to a human in need thereof (a) an antineoplastic agent and (b) an aromatase inhibitor, wherein said agent and said inhibitor are administered in amounts effective to produce a superadditive antitumor effect, and the aromatase inhibitor is not aminogluthetimide when the antineoplastic agent is a combination consisting of cyclophosphamide, doxorubicin and 5-fluorouracyl.

37. (New) The method according to claim 36, wherein the antineoplastic agent is selected from the group consisting of an antineoplastic topoisomerase II inhibitor, an

antineoplastic antimicrotubule agent, an antineoplastic alkylating agent, an antineoplastic antimetabolite and an antineoplastic topoisomerase I inhibitor, and the aromatase inhibitor is selected from the group consisting of exemestane, formestane, fadrozole, vorozole, letrozole, anastrozole and YM 511.

38. (New) The method according to claim 37, wherein the antineoplastic agent is selected from the group consisting of an anthracycline compound, an anthraquinone compound, a podophillotoxine compound, a taxane compound, a vinca alkaloid, an alkylating agent, an antineoplastic antimetabolite agent and an antineoplastic topoisomerase I inhibitor.

39. (New) The method according to claim 38, wherein the anthracycline compound is selected from the group consisting of doxorubicin, epirubicin, idarubicin and nemorubicin; the anthraquinone compound is selected from the group consisting mitoxantrone and losoxantrone; the podophillotoxine compound is selected from the group consisting of etoposide and teniposide; the taxane compound is selected from the group consisting paclitaxel and docetaxel; the vinca alkaloid is selected from the group consisting of vinblastine and vinorelbine; the alkylating agent is selected from the group consisting of cyclophosphamide ifosfamide, melphalan and PNU 159548; the antineoplastic antimetabolite agent is selected from the group consisting 5-fluorouracil, capecitabine, gemcitabine, methotrexate and edatrexate; and the antineoplastic topoisomerase I inhibitor is selected from the group consisting of topotecan, irinotecan, 9-nitrocamptothecin and PNU 166148.

40. (New) The method according to claim 38, wherein 1, 2 or 3 antineoplastic agents is selected from the group consisting of epirubicin, doxorubicin, idarubicin, paclitaxel, docetaxel, 5-fluorouracil, cyclophosphamide and vinorelbine, and 1 or 2 steroidal aromatase inhibitors is selected from the group consisting of exemestane, formestane, anastrozole, letrozole and fadrozole, are administered.

41. (New) The method according to claim 37, wherein the antineoplastic agent is selected from the group consisting of an anthracycline compound and a taxane compound, and the steroidal aromatase inhibitor is exemestane.

42. (New) The method according to claim 41, wherein one or two antineoplastic agents is selected from the group consisting of epirubicin and docetaxel, and the steroidal aromatase inhibitor is exemestane, are administered.

43. (New) The method according to claim 39, wherein:

- an effective antineoplastic amount of vinblastine is from about 3 mg/m<sup>2</sup> to about 10 mg/m<sup>2</sup>;

- an effective antineoplastic amount of doxorubicin is from about 20 mg/m<sup>2</sup> to about 100 mg/m<sup>2</sup>;

- an effective antineoplastic amount of epirubicin is from about 20 mg/m<sup>2</sup> to about 200 mg/m<sup>2</sup>;

- an effective antineoplastic amount of idarubicin is from about 1 mg/m<sup>2</sup> to about 50 mg/m<sup>2</sup>;

- an effective antineoplastic amount of mitoxantrone is from about 10 mg/m<sup>2</sup> to about 20 mg/m<sup>2</sup>;

- an effective antineoplastic amount of paclitaxel is from about 100 mg/m<sup>2</sup> to about 300 mg/m<sup>2</sup>;

- an effective antineoplastic amount of docetaxel is from about 50 mg/m<sup>2</sup> to about 100 mg/m<sup>2</sup>;

- an effective antineoplastic amount of vinorelbine is from about 15 mg/m<sup>2</sup> to about 30 mg/m<sup>2</sup>;

- an effective antineoplastic amount of cyclophosphamide is from about 100 mg/m<sup>2</sup> to about 1500 mg/m<sup>2</sup>;

- an effective antineoplastic amount of melphalan is from about 1 mg/m<sup>2</sup> to about 10 mg/m<sup>2</sup>;

- an effective antineoplastic amount of 5-fluorouracil is from about 100 mg/m<sup>2</sup> to about 1000 mg/m<sup>2</sup>;

- an effective antineoplastic amount of capecitabine is from about 10 mg/m<sup>2</sup> to about 1000 mg/m<sup>2</sup>;

- an effective antineoplastic amount of methotrexate is from about 10 mg/m<sup>2</sup> to about 1000 mg/m<sup>2</sup>;

- an effective antineoplastic amount of topotecan is from about 1 mg/m<sup>2</sup> to about 5 mg/m<sup>2</sup>;

- an effective antineoplastic amount of irinotecan is from about 50 mg/m<sup>2</sup> to about 350 mg/m<sup>2</sup>;

and an effective amount of aromatase inhibitor is from about 0.5 to about 500 mg.

44. (New) The method according to claim 42, wherein the one or two antineoplastic agents and the steroidal aromatase inhibitors are administered orally, the amount of aromatase inhibitor exemestane is from about 5 to about 200 mg, the amount of fadrozole is from about 0.5 to about 10 mg, the amount of letrozole is from about 0.5 to about 10 mg, and the amount of anastrozole from about 0.5 to about 10 mg.

45. (New) The method according to claim 42, wherein the one or two antineoplastic agents and the steroidal aromatase inhibitors are administered parenterally, the amount of aromatase inhibitor exemestane is from about 5 to about 500 mg, and the amount of formestane is from about 250 to about 500 mg.

46. (New) A method for lowering the side effects in humans caused by breast cancer therapy with an antineoplastic agent, said method comprising administering to a human in need thereof a pharmaceutical composition comprising (a) an antineoplastic agent and (b) an

aromatase inhibitor, wherein said agent and said inhibitor is present in a quantity to produce a superadditive antitumor effect, and the aromatase inhibitor is not aminogluthetamide when the antineoplastic agent is a combination consisting of a cyclophosphamide, doxorubicin and 5-fluorouracyl.

47. (New) The method according to claim 40, wherein:

- an effective antineoplastic amount of vinblastine is from about 3 mg/m<sup>2</sup> to about 10 mg/m<sup>2</sup>;
- an effective antineoplastic amount of doxorubicin is from about 20 mg/m<sup>2</sup> to about 100 mg/m<sup>2</sup>;
- an effective antineoplastic amount of epirubicin is from about 20 mg/m<sup>2</sup> to about 200 mg/m<sup>2</sup>;
- an effective antineoplastic amount of idarubicin is from about 1 mg/m<sup>2</sup> to about 50 mg/m<sup>2</sup>;
- an effective antineoplastic amount of mitoxantrone is from about 10 mg/m<sup>2</sup> to about 20 mg/m<sup>2</sup>;
- an effective antineoplastic amount of paclitaxel is from about 100 mg/m<sup>2</sup> to about 300 mg/m<sup>2</sup>;
- an effective antineoplastic amount of docetaxel is from about 50 mg/m<sup>2</sup> to about 100 mg/m<sup>2</sup>;
- an effective antineoplastic amount of vinorelbine is from about 15 mg/m<sup>2</sup> to about 30 mg/m<sup>2</sup>;
- an effective antineoplastic amount of cyclophosphamide is from about 100 mg/m<sup>2</sup> to about 1500 mg/m<sup>2</sup>;
- an effective antineoplastic amount of melphalan is from about 1 mg/m<sup>2</sup> to about 10 mg/m<sup>2</sup>;



- an effective antineoplastic amount of 5-fluorouracil is from about 100 mg/m<sup>2</sup> to about 1000 mg/m<sup>2</sup>;

- an effective antineoplastic amount of capecitabine is from about 10 mg/m<sup>2</sup> to about 1000 mg/m<sup>2</sup>;

- an effective antineoplastic amount of methotrexate is from about 10 mg/m<sup>2</sup> to about 1000 mg/m<sup>2</sup>;

- an effective antineoplastic amount of topotecan is from about 1 mg/m<sup>2</sup> to about 5 mg/m<sup>2</sup>;

- an effective antineoplastic amount of irinotecan is from about 50 mg/m<sup>2</sup> to about 350 mg/m<sup>2</sup>;

and an effective amount of aromatase inhibitor is from about 0.5 to about 500 mg.